Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Cluster Investigation

Guidance on how to proceed with a cluster investigation when reported to a Department of Public Health Medicine / Medical Officer of Health

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List of acronyms

MOH	Medical Officer of Health
CPHM	Consultant in Public Health Medicine (In Ireland this is the same as a Specialist in Public Health Medicine)
WHO	World Health Organization
NALA	National Adult Literacy Agency
DPH	Director of Public Health
PHMEHG	Public Health Medicine Environment and Health Group
PEHO	Principal Environmental Health Officer
SEHO	Senior Environmental Health Officer
EPA	Environmental Protection Agency
NCRI	National Cancer Registry Ireland
HSA	Health and Safety Authority
PHE	Public Health England
CRCE	Centre for Radiation, Chemical and Environmental Hazards
CDC	Centre for Disease Control, US

Report Overview

A cluster is defined as an 'unusual aggregation, real or perceived, of health events that are grouped together in time and space and that are reported to a health agency'[1]. The investigation of reported clusters can be complex and resource-intensive work. Careful consideration must be given in the early stages to understanding the concerns of the stakeholders; fostering and developing a communication channel with them and undertaking appropriate and evidence based investigations into the concerns. The investigations should be regularly re-assessed and the results and progress of the investigation should be communicated through the identified channels. When there is insufficient evidence to justify proceeding further, the investigation should be adjourned. The possibility of this should be communicated to the stakeholders at the start of the investigation. Once a decision to adjourn the investigation has been made, this should be communicated to the stakeholders.

This guidance will contain four short sections.

Section 1: Introduction and Communication

This section will focus on the importance of early good communication with whoever reports concerns that a cluster of health events exists.

Section 2: Pathway for Managing Cluster Investigations

This section will outline the stages on how to undertake a cluster investigation. This pathway has been developed broadly based on the 2015 New Zealand guidance[2].

Section 3: Report write up and Communication

This section outlines the importance of appropriate clear communication back to the stakeholders on the investigation. Any follow up steps or recommendations for preventative care can be highlighted at this point.

Section 4: Useful Resources

This section will provide links to web pages, documents and telephone numbers that might be relevant when investigating a report of an environmental cluster.

Section 1: Introduction and Communication

Introduction

Due to the complex nature and uncertain outcomes from an environmental cluster investigation, establishing trust and credibility at the outset of any such investigation is of paramount importance. Establishing roles and responsibilities of those who will be involved in the cluster investigation is key.

Roles and Responsibilities

Clusters of diseases are notifiable under Infectious Diseases Regulations, 1981 as amended. SI No. 707 of 2003 - Infectious Diseases (Amendment)(No. 3) Regulations 2003[3] added 'disease clusters and changing patterns of illness that may be of public health concern' to the conditions that must be notified to the Medical Officer of Health (MOH) who in turn informs the Health Protection Surveillance Centre. In addition MOHs shall inform themselves 'as respects all influences affecting or threatening to affect injuriously the public health in the county and as respects the causes, origin and distribution of diseases in the county' under the Health (Duties of Officers) Order, 1949. Therefore, the MOH has the legal responsibility for the investigation of the cluster and to control it if it is of infectious origin, or to advise on control if the cause is non-infectious. As part of the investigation they will likely require a team (cluster investigation team) to help inform the cluster investigation, specifically with environmental expertise. The role of each member and the overall governance of the group should be outlined clearly by the MOH.

GDPR

It is important to be compliant with GDPR. An article 6 basis 'lawfulness of processing' should be determined. This could be one of the following; consent; public interest; compliance with law; legitimate interest. As health data are special category data an article 9 condition should also be determined. This could be 9(2)h 'preventive medicine or provision of services', or 9(2)i 'reasons of public interest in the area of public health'.

Communication

Developing and maintaining effective communication skills with the informant or group concerned, regarding the possibility of a cluster is crucial to the satisfactory outcome of the cluster investigation. There will likely be uncertainty, in terms of quantity and quality, around the availability of information that is required for the cluster investigation. This uncertainty should be acknowledged. It should also be recognised that whilst it is possible that a cause for a cluster can either be proven or disproven, often the results of the investigation will leave uncertainty between these two definitive outcomes. For example, following on from the investigation we might suspect causation but are unable to prove it. Equally we might not suspect causation but be unable to prove this absence of an association or effect. The success of a cluster investigation requires reaching a satisfactory outcome that is understood and accepted by all stakeholders. It is also possible with cluster investigations, that although no environmental cause is identified, the investigation highlights the impact of health inequalities in a geographical location, for example, the effects of smoking. This is an opportunity for the Consultant in Public Health Medicine (CPHM) to work with the community to help reduce these health inequalities.

'Risk communication is a two way process'[3] and therefore a two-way communication channel should be arranged, whereby the CPHM can contact the key stakeholders to ask any further details and to update and inform them on the progress of the investigation. The stakeholders also need a defined channel mechanism whereby they can make contact with CPHM.

The Alberta Health Services (2011) guidelines[4] suggests key communication milestones. These include establishing open and ongoing communication; role identification and clarity; information provision; quality assurance and final presentation of results.

The World Health Organization (WHO)[5] published a document on 'Health and environment: communicating the risks' where they identify that risk perception varies according to your audience. They discuss the 'Sandman formula' which

states that risk perception is formed by two components – hazard (technical scientific component) and outrage (subjective component). They suggest that outrage consists of many factors, including:

- the involuntary nature of the risk
- the artificial (industrial) nature of the risk
- the use of cover up (silence)
- attempts to persuade about the issue
- occurrences of accidents
- double truths around the issue
- conflicts of interest
- contradictory messages
- inequitable distribution of risk

Crucially, they note that 'a sense of outrage can distort risk perception'. They further note that uncertainty should be acknowledged as a central component in managing environmental risks.

We also know from research that the public perceive risks differently depending on who presents the risk and how the risk is presented.

The WHO report a study conducted in the UK by the Consumers' Association (McKechnie and Davies 1999) who surveyed over 2000 adults about whom they considered to be trustworthy sources of impartial advice[6].

Source	Most trustworthy (%)	Least trustworthy (%)
Health professionals (e.g. GPs, health visitors)	36	3
Consumer organisations (e.g. National Consumer Council, Consumers' Association)	27	4
Scientists specializing in food safety	20	5
Government Departments	5	49
The food industry	5	30

This clearly shows the value and trust placed in health-care professionals and, to a slightly lesser extent, consumer organisations and associations. It is

therefore imperative that this trust is maintained by the manner in which the investigation is conducted and with the personnel we might include as part of the investigation.

The UK Department of Health has produced 'Communicating about Risks to Public Health: Pointers to good practice'[7]. They state that

- Messages are usually judged first by whether their source is trusted
- Intentional communication is often only a minor part of the message actually conveyed
- Responses to messages depend not only on content but also on manner of delivery, **especially emotional tone**
- Experts no longer command automatic trust
- Trust is generally fostered by openness, both in the sense of avoiding secrecy and in being ready to listen.

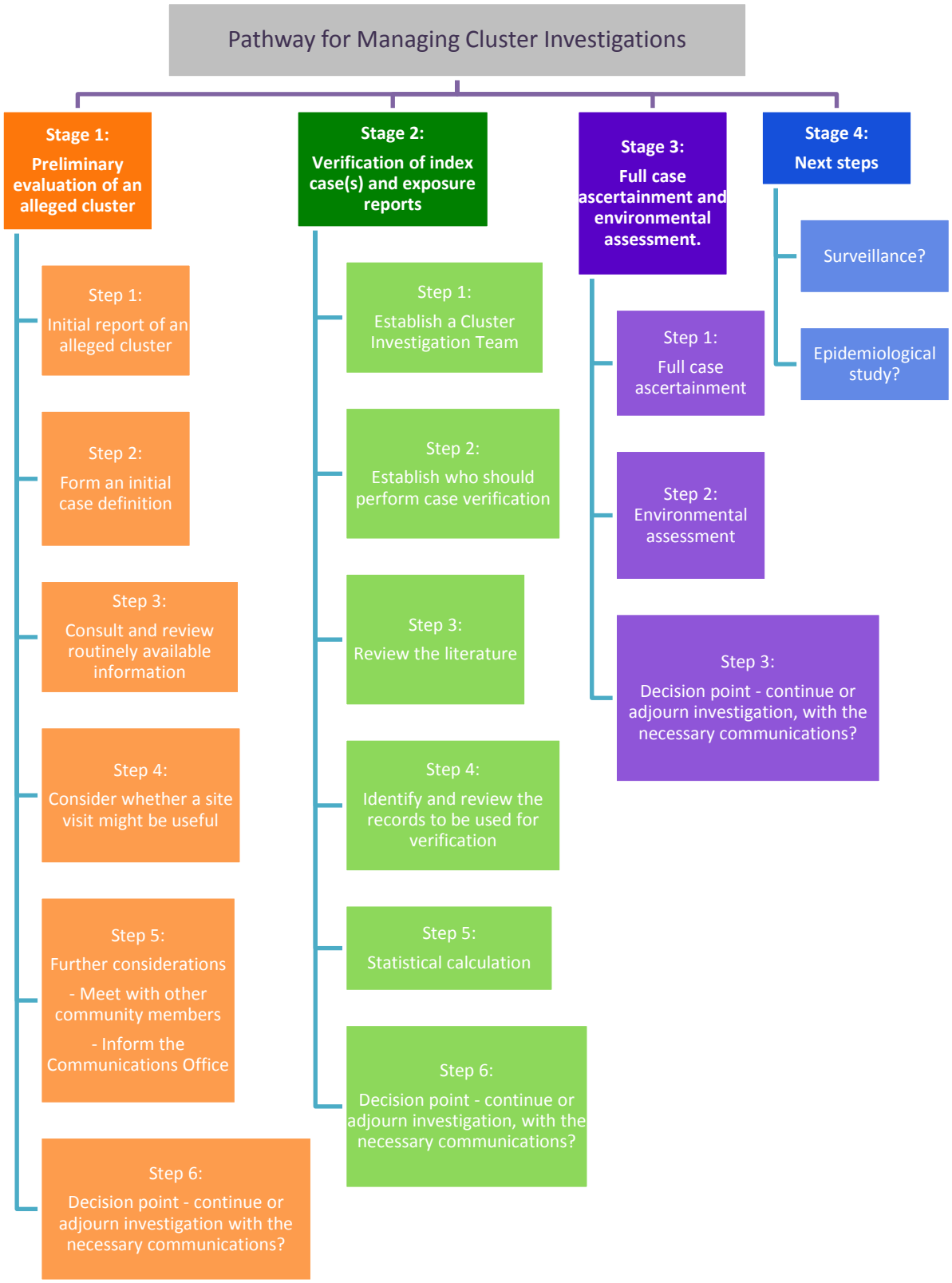
We also know that when asked, people overwhelmingly wish to be informed through face-to-face contact first, with written materials provided to back-up this information or to be used as a second-choice method of communication. For these written materials, there is literature available on the style in which our investigation should be presented, most specifically with regard to the use of simple clear language and simple clear presentation of data. The National Adult Literacy Agency (NALA)[8] provides advice and assistance with this presentation of information and data such that we can maximise the audience we can reach.

Summary points of best practice in Communication

It is clearly important that we try and apply these communication and risk perception points when managing an alleged environmental cluster.

- Identify a clear communication channel such that the cluster team can contact the key stakeholders and vice versa
- Clarify the difference between :
    - the role of Public Health (PH) in assessing and investigating the significance of possible health impact upon a population and the role of other agencies (planning, environmental and health and safety authorities) as regulators and decision makers
    - the Public Health role in assessing population health impact and the role of clinicians in assessing individual health impact which require the consent of each relevant individual for PH access to their confidential medical records.
- Establish clear Governance of the investigating group
- Investigate in a clear open and transparent way

Section 2: Overview Pathway for managing cluster investigations



Section 2: Pathway for managing cluster investigations

Stage 1: Preliminary evaluation of a suspected cluster

Step 1: Initial report of a cluster

It should be noted that clusters might be notified in different ways and at different stages of the investigation process. It might be initially reported by a member of the public, when they develop a particular concern, or, a cluster might be reported by for example, the National Cancer Registry of Ireland (NCRI) after they have undertaken sophisticated epidemiological work. At any stage when a CPHM is notified of a cluster, they should listen to the concern and explore all the detail available with regard to the concern, to date.

When the initial report of a suspected cluster is made to the Department of Public Health the CPHM should promptly elicit as much initial information as possible about the cluster and what the informant thinks may be the cause. A template cluster notification form is presented in Appendix One. Discuss your initial impressions with the caller. It might be possible and appropriate at this point to provide some health education on the reported disease. An estimated 75% of reported clusters can be resolved at this initial stage of contact[9]. This may still take some time e.g. a few hours up to a full day, depending on the issue.

The CPHM should explain how complex cluster investigations can be, and that often no satisfactory explanation is found. However, it is important to try and address the concerns, inform the caller of the next steps that will be taken, and put this in writing to them. If you decide based on the information received that there are no grounds for continuing the investigation, document this and communicate directly to the caller. A letter to this effect should be issued to the caller and maintained as a record of the query.

If you feel that there are grounds for further assessment proceed to step 2.

An example of a ‘cluster notification form’ is provided in Appendix One.

Remember:

- A variety of reported conditions make a common cause unlikely.
- Do not commit to an extensive study at this stage.
- The CPHM should explain how complex cluster investigations are performed, and that often no satisfactory explanation is found.
- However, try and address the caller's concerns.
- Inform the caller of the next steps that you will take, and put this in writing to them.
- If you decide based on the information received that there are no grounds for continuing the investigation, document this, and issue a report to this effect to the caller.

Step 2: Form an initial case definition

The initial case definition is based on the following questions:

- What is the specific disease, symptom or health event of concern?
- Where is the affected geographical area, population group or workplace?
- When did the specific disease, symptom or health event occur?
- Who (e.g. age, ethnicity, sex) are the index cases (i.e. the cases first reported)?
- What, if any, are the suspected specific exposures?

Step 3: Consult and review routinely available information

This might include:

- A review of national registers
- A review of routinely available health and mortality data
- A focused literature review regarding the suspected environmental cause and risk factors for the health condition
- A review of planning/licensing information if relevant e.g. in the case of an alleged source which is regulated by the Local Authority, the EPA, Comreg or the Health and Safety Authority etc.
- Consulting with your Director of Public Health (DPH) / CPHMs / Public Health Medicine Environment Health Group (PHMEHG) / Environmental

Health colleagues who may have knowledge and expertise on the health condition, the suspected exposure and/or the geographical area

Step 4: Consider whether a site visit might be useful to

- get information on possible environmental exposures
- identify where these exposures are in relation to the population under consideration
- understand if there is a possible pathway through which these exposures might have affected the local population

Step 5: Further consider whether it might be useful to

- consult with local GPs, Public Health Nurses (PHNs) and Emergency Department Services about any changes in local morbidity patterns
- meet with other members of the community where the suspect cluster is
- inform the Communications Office

Step 6: Make a decision – Continue or end the Investigation?

In general, further investigation is warranted if any one of the following conditions exists[10].

- an unusually high number of cases
- unusual type of disease
- an unusual age group
- a biologically plausible exposure(s)
- adequate latency for the reported disease
- intense community concern

Ending the investigation

If a decision is made to end the investigation, the following actions are recommended[11]:

- Write a report with a summary and conclusion
- Communicate the results to the key stakeholders through the agreed communication channel. This should likely be an initial brief verbal communication followed by a comprehensive written communication.
- Appropriate relevant health advice should also be given at this point e.g. health education and screening programmes.

Continuing the investigation

If a decision is made to continue with the investigation, the stakeholder should be informed. Clear leadership, terms of reference, limits and definitions need to be established for the investigation.

Stage 2: Verification of index case(s) and exposure reports

This stage involves confirming that there is:

a) an excess of cases meeting the case definition, and
b) a recent exposure to a biologically plausible causal agent for the type of disease reported

Step 1: Establish a Cluster Investigation Team

The team should be led by the MOH. Further membership of the team will vary in size and agencies represented depending on the nature and seriousness of the suspected cluster but may include:

1. DPH and / or CPHM (MOH lead)
2. Research Officer
3. Surveillance Scientist
4. Support Staff
5. Principal Environmental Health Officer (PEHO) and / or SEHO
6. Representative from Communications
7. Representative from the EPA
8. Representatives from other relevant agencies, e.g. NCRI / Health and Safety Authority (HSA)

The roles and responsibilities of each member of the Cluster Investigation Team should be clarified at the outset.
The National MOH should also be informed and kept updated on progress.

Step 2: Establish who should do the verification.

- Contact should be made with the index cases to seek their consent in writing for review of their medical records. For suspected cancer cases, the NCRI will perform the case verification.
- For a suspected work-based cluster, liaise with the HSA as to who should perform case verification.
- For a suspected congenital anomaly cluster data should be used from the congenital anomaly register if available, with an assessment made for the registers level of completeness

- All other case verification should be completed by the Public Health MOH

Confidentiality of all cases should be maintained throughout.

Step 3: Review the literature

A systematic literature review should be completed on the biology and risk factors for the disease, including its natural history and latency period.

Step 4: Identify and review the records to be used for verification

These include:

- death certificates,
- medical records, including pathology reports
- population-based registries
- employment records.

Step 5: Statistical calculation

The suspect cluster should be described epidemiologically in terms of disease, person, place and time with simple descriptive statistics. For diseases where there is a population register, there will be reasonably accurate information about all cases living within the area being investigated. In addition, if the numbers allow it, analysis should be performed to determine whether or not there is any increase in the number of cases above what we expect to see in this population i.e. to see if there is a statistically significant excess of cases in the area compared to a reference population. The standardised incidence ratio (SIR), or standardized mortality ratio (SMR) are commonly used for this. Choosing the denominator requires careful consideration; it should be a population which includes all those who *could* be exposed, it should represent the population from which the cases come and it should represent the population to whom the findings will be generalised. Bear in mind that data may not be available at the level you would like, particularly small area data.

Step 6: Make a decision

Based on the information collected during Stage 2, a decision should be made by the MOH with the assistance of the Cluster Investigation Team whether to conclude the investigation at this stage, or proceed further.

Criteria for continuing include:

- an excess number of cases identified
- evidence of sufficient exposure (time and magnitude) to a biologically plausible agent for the disease
- continuing serious public concern
- further investigation is feasible.

If the above criteria are not fulfilled the investigation should be concluded. Concluding the investigation should be performed, as per stage 1 step 6.

Stage 3: Continuing the investigation. Full case ascertainment and environmental assessment

This stage will require additional resources and expertise beyond that available within the Department of Public Health.

Step 1 - Full case ascertainment

This involves finding and verifying all additional unreported cases of the disease in question in the time period and geographical area of interest. Recommended steps are:

1. Establish a case-finding multi-disciplinary team
2. Refine the case definition, if necessary, in terms of:
    a. Disease
    b. Time period
    c. Geographical area or population group
3. Develop and implement the case-finding strategy
    a. Decide what records need to be examined
    b. Determine what data will be collected
    c. Collect the data, mindful of data protection and ethical duties.
    d. Consider if research ethics review is necessary. Frequently such investigations fall under Infectious Disease and or/Duties of Officers legislation and research ethics review is not required. The legislation under which the investigation is taking place should be clear and stated in writing early on.
4. Count and analyse case data

Step 2 - Environmental assessment

The purpose of environmental assessments is to identify a cause or seek a plausible causal process for the cluster of a specific disease. This stage should involve an expert in environmental health or environmental science.

Step 3: Make a decision

Further investigation is usually not required if there is:

- no excess disease and no exposure,

- no excess disease, a possible exposure, but no connected biological plausibility
- excess disease, no identified exposure and no biological plausibility that the excess rate results from an environmental exposure.

If there is an excess of cases, consider the following questions.

- Is it of concern?
- Is further study required?
- Is the exposure biologically plausible?
- Have cases increased suddenly in a recent period?
- Are there more cases observed than would be expected for time and place?
- Can the population at risk be defined?
- If cancer, is the type of cancer or age of onset unusual?
- If cancer, are there documented, prolonged exposures to known or suspected carcinogens at levels exceeding environmental limits?

In general, a 'yes' answer to most of these questions increases the need for further follow-up (Stage 4).

If the above criteria are not fulfilled the investigation should be concluded. Concluding the investigation should be performed, as per stage 1 step 6.

Stage 4: Surveillance or epidemiological study

This stage should only be undertaken with the approval of the Assistant Director of Health Protection / National MOH.

Surveillance

When an excess number of cases are found in the cluster, through passive surveillance using routine information systems that are already in place such as the National Cancer Registry of Ireland (NCRI) or other disease registries or other sources of morbidity data such as HIPE, CIDR etc. enhancing the surveillance of disease rates over a period of years may be more appropriate than embarking on an epidemiological study. It can be difficult to design and

execute an epidemiological study with sufficient statistical power to disprove the null hypothesis and the putative exposure may have poor biological plausibility. It may be more appropriate to establish an active surveillance system involving the notification of illness by health professionals.

Epidemiological study

An epidemiological study should be undertaken if there is an excess of cases and they have a biologically plausible connection with some environmental exposure. This can be a case-control, cohort or cross-sectional study. Consultation with appropriate specialists and agencies is recommended.

Section 3: Report write up and Communication

Careful communication with stakeholders is required at this stage.

Cluster investigations often don't identify findings consistent with the initial query - either no true cluster is identified, or no cause is identified. However, the success of the investigation does not depend on these findings, more on the communication and interaction with the stakeholders who are most concerned. Maintaining good effective communication throughout the process of the environmental investigation will assist with the presenting and acceptance of the final investigation findings.

It is well understood that people accept better any report findings if they are informed in person, as well as receiving supporting written information.

Providing an opportunity for the stakeholders to be informed of the findings, ask any remaining questions and voice any remaining concerns is important. There are often areas where Departments of Public Health can offer health advice, or provide support and advocacy for health or environmental justice.

The report write-up should be clear, transparent and representative of the investigation, highlighting both the certainty of what we know, and the

uncertainty around the investigation and its findings. A written report should be made available for the stakeholders.

Section 4: Useful resources

Information Sources, Ireland

CSO Census detail

The Health Well PHIS data tables

The Health atlas Ireland

Congenital Anomaly Register, Ireland

Eurocat network (clusters and trends)

National Perinatal Reporting System

Irish cancer registry

EPA Irelands environment

EPA licensing

EPA GIS

Dept Environment, Community and Local Government

Health & Safety Authority

International Information Sources

Public Health England. Guidance for investigating non-infectious disease clusters from potential environmental causes

Public Health England Centre for Radiation, Chemical and Environmental Hazards (PHE CRCE)

UK Toxbase

US Toxicology data network

ATSDR Toxic Substances Portal

US Office of Environment, Health, Safety and Security (EHSS)

International Programme on Chemical Safety.

International Programme on Chemical Safety Environmental Health Criteria

PHE Health Protection

Software for analysing and mapping clusters

Cluster toolkits and examples

United Kingdom and Ireland Association of Cancer Registries

CDC information on cluster investigation

CDC guidelines for investigating clusters of health events

The National Public Health Information Coalition

Scottish guidance document for environmental health exposures

MND Cluster Investigation, New Zealand

Communication and Risk perception

WHO 'Health and Environment: communicating the risks'

DOH 'Communicating about risks to public health: pointers to good practice'.

Ministry of Health New Zealand 'Investigating clusters of Non-Communicable Disease. Guidelines for Public Health Units.

Useful Phone Numbers

Environmental Protection Agency 053 9160600

Health and Safety Authority 1890 289 389

Radiological Protection Institute of Ireland 01 2697766

National Cancer Registry Ireland 021 431 8014

Public Health England National Chemical Hotline (24 Hours): 0044 344 892 0555. Routine Public Health Enquiries: Tel: 0044 2920 416388, Fax: 0044 2920 416387, Email: chemicals.cardiff@hpa.org.uk ;

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Appendix One

Cluster notification form

Name of person completing form:

Date

Informant

First Name | Surname

Address

Telephone | Mobile

E-mail

Background of informant:

Media (specify)

Family member of case (specify relationship)

Friend of case | Doctor

Description of the problem

How did the informant come to believe there might be a problem?

Setting of the suspected cluster:

Neighbourhood (specify)

School (specify)

Workplace (specify)

Other (specify)

Is there a suspected exposure?

☐	Yes (specify)

☐	No

If possible get the following information from the informant about each case

(please print as many pages as required)

Index case (number, 1 or 2 etc)

First Name **Surname**

Most recent address

How long has the person lived there?

Telephone **Mobile**

Age / / **Date of birth** / /

Ethnicity

Diagnosis

Basis of diagnosis

Date of diagnosis / /

Date of death / / **Place of death**

Next of kin

Contact details for next of kin

Physician details

Suspected environmental exposures:

Type of exposure

Address where exposure occurred if different from above address

Date exposure began / /

Date exposure ended / /

Details of changes in exposure (e.g. when, extent, duration)

Smoking history (year started, duration, amount / day, tobacco type (e.g. cigarettes))

Occupational history:

	Type of industry	Job	Year job began	Year job ended
Present job				
Previous job				
Job before that				
Job before that				

Any other details from informant

Is the informant willing to assist in providing further information if necessary?

☐ Yes

☐ No